A randomised controlled trial of trans-anal versus trans-vaginal repair for symptomatic anterior rectocoele

Submission date	Recruitment status	Prospectively registered
29/09/2006	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
29/09/2006	Stopped	Results
Last Edited	Condition category	Individual participant data
03/09/2013	Urological and Genital Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number N0050166862

Study information

Scientific Title

Study objectives

A rectocoele is a common problem caused by weakness in the tissues of the pelvis, which leads to problems with defecation. A number of surgical approaches to repair of a rectocoele are available. Currently in our institution a patient will have rectocoele repair either through the anus or through the vagina. No consensus of opinion exists as to which is the superior approach. The aim of this study is to randomise the patients to one or the other operation to establish which approach is superior.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Urological and Genital Diseases: Rectocoele

Interventions

Patients will be selected from the clinics for suitability for surgical repair of their rectocoele following appropriate investigations. All patients will be assessed in a structure manner. A specific questionnaire will be filled in by the patient preoperatively. This questionnaire includes SF-36v2 global quality of life assessment tool, the Cleveland continence scoring toll and specific questions on defecation habits, and dyspareunia.

The presence of a symptomatic rectocele in the absence of other pathology renders the patient suitable for inclusion into the trial and after providing adequate information and fully informed consent they will be randomised to transanal or transvaginal repair. This would happen preoperatively to allow the patient to be counselled and consented about the exact procedure they will undergo.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Functional outcome and quality of life changes by the surgery.

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/02/2006

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria

Research participants will be recruited from the outpatient clinic once they have been identified by preoperative investigation to be suitable for surgical repair of their rectocoele. Inclusion criteria:

- 1. The presence of excessive straining, incomplete evacuation
- 2. The requirement for perineal/vaginal digital pressure during defecation
- 3. Vaginal bulging and constipation, due to a rectocoele as proven on defaecography, in the presence of a normal large bowel.

These are standard indications for rectocoele repair.

62 patients will be recruited in to the study from the department of Colorectal Surgery and Gynaecology, 31 patients will be in each arm.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Patients with a slow transit colon or sphincter defects as these patients have been shown not to benefit from rectocoele repair.

Date of first enrolment

02/06/2005

Date of final enrolment

01/02/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Bradford Royal Infirmary Bradford United Kingdom BD9 6RJ

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type

Government

Funder Name

Bradford Teaching Hospitals NHS Foundation Trust (UK) Own Account

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration